IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-956 (MSG)
	)	
ACCORD HEALTHCARE, INC.,	)	
	)	
Defendant.	)	

AMGEN'S OPENING CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's Scheduling Order (D.I. 27), and in view of the Final Joint Claim Chart (D.I. 66), Plaintiff Amgen Inc. ("Amgen") submits this Opening Claim Construction Brief in support of its proposed construction of the two disputed claim terms in U.S. Patent No. 9,375,405 ("the '405 patent," Rothman Decl. Ex. 1).[1] For the reasons discussed below, Amgen's claim constructions are supported by the intrinsic evidence and the ordinary and customary meaning of the claim terms as understood by a POSA. Thus, Amgen respectfully requests that the Court adopt its proposed constructions.

NATURE AND STAGE OF THE PROCEEDINGS

This Hatch-Waxman action arises from the filing of an Abbreviated New Drug Application ("ANDA") by Defendant Accord Healthcare, Inc. ("Accord") seeking to market generic versions of Amgen's Sensipar® tablets prior to the expiration of the '405 patent.[2] On January 28, 2019, the Court entered a Scheduling Order (D.I. 27) authorizing Accord to file a motion for summary judgment of non-infringement, and setting a schedule for fact discovery, claim construction, and expert discovery. Accord filed its motion for summary judgment on February 1, 2019. On March 1, Amgen responded and cross-moved under Fed. R. Civ. P. 56(d), seeking an order denying Accord's motion until Amgen was afforded an opportunity to conduct further fact discovery, claim construction, and expert discovery pursuant to the Scheduling Order. Both motions are currently pending before the Court.

[1] In support of this Opening Claim Construction Brief, Amgen submits herewith the declarations of Joshua I. Rothman, Esq. ("Rothman Decl.") and Amgen's expert Dr. Robert O. Williams III. Dr. Williams' declaration sets forth his opinions on certain scientific issues concerning the pharmaceutical compositions claimed in the '405 Patent ("Williams Decl."). The exhibits referenced herein can be found as attachments to the declarations.

[2] This action is related to C.A. No. 16-853-MSG, which is currently on appeal at the Court of Appeals for the Federal Circuit (Nos. 2018-2414, 2019-1086, 2019-1650, 2019-1770).

On May 3, 2019, Amgen sent Accord a list of three terms for construction and Accord did not initially propose any terms for construction.[3] On June 7, the due date of the Final Joint Claim Chart, Accord finally sent Amgen its proposed constructions of the disputed claim terms. Accord and Amgen agreed that "relative to the total weight of the composition" should be construed as "relative to the total weight of the composition, including coating materials," clarifying the plain and ordinary meaning of that term based on Judge Sleet's claim construction opinion in the previous litigation. *See* D.I. 186 in C.A. No. 16-853, at 1-2 n.1. The parties thereafter filed the Final Joint Claim Chart with the Court (D.I. 66) as to the two remaining disputed claim terms, "from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof" and "hydroxypropyl methylcellulose."

STATEMENT OF FACTS

The claims of the '405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride and pharmaceutically acceptable excipients for the treatment of various diseases, including hyperparathyroidism and hypercalcemia. Claim 1 of the '405 patent is reproduced below, with the claim terms in dispute emphasized:

> 1. A pharmaceutical composition comprising:
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
>
> (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,
>
> **(c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose,**

[3] As set forth in Amgen's Initial Infringement Contentions, served March 18, 2019, Amgen currently plans to assert claims 1-4, 6, 8, 9, 14, 15, and 17-20 of the '405 patent against Accord.

> **hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof**; and
>
> (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidine, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,
>
> wherein the percentage by weight is relative to the total weight of the composition,
>
> and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

'405 patent, Rothman Decl. Ex. 1, col.13, ll.18-39 (emphasis added). Independent claim 20, the only other independent claim currently asserted against Accord, contains an identical element (c). *Id.* col.14 ll.28-50. Claims 1 and 20 cover Amgen's Sensipar® product.

ARGUMENT

I. Legal Standard

The claims of a patent define the scope of the invention and the patentee's rights. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996); *see also* 35 U.S.C. § 112, ¶ 2. A court construing a patent claim seeks to give the claim the meaning it would have to a POSA at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1321 (Fed. Cir. 2005) (*en banc*) ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent."). Claims are construed as "necessary to resolve disputes about claim terms and to assign a fixed, unambiguous, legally operative meaning to the claim." *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004). Claim construction is an issue of law for a court to decide. *Markman*, 52 F.3d at 979. A district court must construe a claim term when the parties present a "fundamental dispute regarding the scope" of the term. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1361-63 (Fed. Cir. 2008).

When construing claims, the "analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (alterations in original) (quoting 35 U.S.C. § 112, ¶ 2); *see also Phillips*, 415 F.3d at 1311-12. Thus, claim construction begins with a determination of the "ordinary and customary meaning" a term would have to a POSA, "in the context of the particular claim in which the disputed term appears." *Phillips*, 415 F.3d at 1312-13.

When interpreting the claims of a patent, courts must view the claims in the context of the "intrinsic" evidence, namely the claims themselves, the specification of the patent, and the prosecution file history (i.e., the back and forth communications between the patent applicant and the United States Patent and Trademark Office ("Patent Office")). *Phillips*, 415 F.3d at 1313-14; *Markman*, 52 F.3d at 979-80. The specification is "highly relevant" to interpreting claim terms and can be the "single best guide to the meaning of a disputed term" due to its statutory role in describing the "claimed invention in 'full, clear, concise, and exact terms.'" *Phillips*, 415 F.3d at 1315-16. In addition to the specification, the prosecution file history may provide insight into how the Patent Office and the inventor understood the claim term. *Id.* at 1317; *Markman*, 52 F.3d at 980. The prosecution file history "is often of critical significance in determining the meaning of the claims." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

A court may also turn to extrinsic evidence, such as expert testimony, when doing so may assist the court in interpreting a particular term or terms. *Phillips*, 415 F.3d at 1317-19 (extrinsic evidence may be helpful to "establish that a particular term in the patent . . . has a particular

meaning in the pertinent field," "explain how an invention works," or "provide background on the technology at issue"); *Markman*, 52 F.3d at 980 ("The court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent.") (citations omitted); *see also AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1249 (Fed. Cir. 2001) (holding that "failure to take into account the testimony of persons of ordinary skill in the art may constitute reversible error"). However, extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. *Phillips*, 415 F.3d at 1318-19, 1324; *Markman*, 52 F.3d at 981.

II. Person of Ordinary Skill in the Art

Dr. Robert O. Williams III opines that a POSA with respect to the '405 patent would generally have been a person with a doctoral degree in pharmacy, chemistry, or a related discipline, and at least two years of practical experience in the field of pharmaceutical formulation. Alternatively, a POSA could have had a lesser degree in one of these disciplines if he or she had at least four years of practical experience in the field of pharmaceutical formulation. Williams Decl. ¶¶13-15.

III. Claims 1 and 20 Element (c): "from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof"

Claim Term	Amgen's Proposed Construction	Accord's Proposed Construction
"from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof"	"from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof, which are capable of forming liquid bridges that harden upon drying,	"from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof, and

(claims 1, 20)	and the pharmaceutical composition may contain unlisted binders (other binders outside the group)"	no unlisted binder"

The parties dispute two issues with respect to this term. First, the parties dispute whether the pharmaceutical composition may contain unlisted binders. Under Amgen's proposed construction, which is supported by the claim language, the specification, and expert testimony, the pharmaceutical composition may contain unlisted binders. Because the claim construction from the previous litigation is on appeal, and because Amgen did not have the opportunity to submit expert testimony or engage in a *Markman* hearing prior to this claim term being construed in the previous litigation, Amgen should not be precluded from having this claim term construed now, aided by expert testimony from Dr. Williams.

Second, the parties dispute whether element (c) should be construed to reflect the type of binders that are actually claimed. Only Amgen's proposed construction recognizes that a person of ordinary skill in the art ("POSA") would have understood that povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, and sodium carboxymethylcellulose can all function as hardening binders in pharmaceutical formulations prepared using wet processing techniques, i.e., they are all binders "capable of forming liquid bridges that harden upon drying." It is Amgen's position that this aspect of the claim must be construed before the Court decides the issues of infringement under the doctrine of equivalents, prosecution history estoppel, and the field of foreseeable equivalents.

A. The Pharmaceutical Composition May Contain Unlisted Binders

A POSA would have understood that the pharmaceutical compositions of claims 1 and 20 are not closed to other unlisted binders (or other unlisted excipients) for at least three reasons:

(1) a POSA reading the claim language would have understood that the claimed excipients have multiple functions, necessitating this construction; (2) claims 1 and 20 use the open-ended claim term "comprising" after the preamble which allows for additional unrecited excipients in the composition; and (3) the specification and file history evidence further supports Amgen's view that the claims are not closed to additional binders. Moreover, Amgen is not collaterally estopped from arguing this claim construction position because Amgen is appealing the Court's claim construction ruling and Amgen did not have a full and fair opportunity to present expert testimony or engage in a *Markman* hearing prior to this claim term being construed in the previous litigation.

1. Claims 1 and 20 List Pharmaceutical Excipients That Can Have Multiple Functions

A POSA reading the language of '405 patent claims 1 and 20 would have understood that the claim language would not make sense unless Amgen's proposed construction is adopted. A POSA would have known that the claimed excipients have multiple functions, which necessitates adopting Amgen's proposed construction. Williams Decl. ¶¶26-27. For example, claims 1 and 20 list pregelatinized starch and microcrystalline cellulose as diluents that satisfy claim element (b). Indeed, in the example provided in the '405 patent, one of the ingredients is pregelatinized starch. *Id.* ¶28. A POSA would have understood that pregelatinized starch can have multiple functions; in addition to functioning as a diluent in a particular formulation, it can also exhibit binding and disintegrating characteristics, even in the same formulation. *Id.* ¶29. The same is true for microcrystalline cellulose, which is included in the patent example and is categorized as a diluent in claims 1 and 20. *Id.* ¶30.

Imposing a requirement that an excipient well known to be multi-functional have only a single function in the claimed pharmaceutical compositions, as Accord's proposed construction

does, would be contrary to the basic understanding of a POSA regarding pharmaceutical formulations and the language of claim 1. Indeed, if the claimed compositions could not contain any "unlisted binders" whatsoever, then a composition comprising MCC and/or starch, which function as a binder, would be excluded from the claims, even though those excipients are expressly permitted by claim 1 element (a). Based on the plain reading of claims 1 and 20, a POSA would have understood that the claims require the presence of one or more of the listed binders in an amount from about 1% to about 5% by weight. But a POSA would have also understood that the listed excipients can have additional functions other than those set forth in the claims, and therefore a pharmaceutical composition still falls within the scope of claims 1 and 20, even though excipients present in the formulation—including the binders, diluents, and/or disintegrants listed in claims 1 and 20—have additional functions. Thus, viewing the claim language from the perspective of a POSA supports Amgen's view that the pharmaceutical composition may contain unlisted binders, i.e., other binders outside the group.

2. Claims 1 and 20 Use the Open-Ended Term "Comprising"

Amgen's proposed construction is also correct because independent claims 1 and 20 use the open-ended term "comprising" following the preamble, which is not limiting and allows for additional excipients outside of the listed group. *See, e.g.*, *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) ("In the patent claim context the term 'comprising' is well understood to mean 'including but not limited to.'"); *Georgia–Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999) ("The transitional term 'comprising' . . . is inclusive or open-ended and does not exclude additional, unrecited elements[.]").

Element (c) imposes some limits on the claimed compositions, but it does not foreclose the use of unlisted binders. To be sure, claim terms "set off by the transitional phrase 'consisting of'," like element (c), are generally "closed to unrecited elements." *Multilayer Stretch Cling Film*

Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016). But that does not end the inquiry because it is "necessary to determine what is limited by the 'consisting of' phrase." *Norian Corp. v. Stryker Corp*., 363 F.3d 1321, 1331 (Fed. Cir. 2004). Here, that phrase sets off "the group" from which "at least one" binder must be selected—nothing more. Additional excipients are not excluded.

The remainder of the claim confirms that understanding. Indeed, the Federal Circuit has recognized that the "open-ended" meaning of "comprising" may persist even when other language imposes restrictions on the scope of particular claim elements. For example, when the limiting phrase "consisting of" appeared in one sub-clause of a claim under consideration but "not the preamble," the Federal Circuit held that the language "limit[ed] only the element set forth in" the clause and did not "exclud[e] all other elements from the claim as a whole." *Mannesmann Demag Corp. v. Engineered Metal Prods. Co*., 793 F.2d 1279, 1282-83 (Fed. Cir. 1986). Similarly, in *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004), a claim covered a "purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO: 1, wherein said portion consists of the nucleotide sequence from 521 to 2473 of SEQ ID NO:1[.]" *Id.* at 1254-55 (emphasis added). Rejecting the accused infringer's narrow construction, this Court held that "the term 'consists of' only limits the 'said portion' language directed to the subsequently recited numbered nucleotides, but the earlier term 'comprising' means that *the claim can include that portion plus other nucleotides*." *Id*. at 1257 (emphases added). "Read in context," therefore, the claims did "not preclude a DNA sequence having additional nucleotides." *Id.*

Here, as in *Mannesmann* and *Crish*, the term "consisting of" does not serve as a limit on the entire claim. It limits the "at least one" binder or disintegrant to those listed in element (c),

but "the earlier term 'comprising' means" that other binders or disintegrants may also be in the composition. Consequently, Amgen's proposed construction is correct because it is the only one that gives effect to both the "consisting of" and "comprising" language recited in claims 1 and 20.

3. The Specification and File History Support Amgen's Proposed Construction

The '405 patent specification provides an *exemplary* list of excipients that may be used as binders in the pharmaceutical composition recited in claims 1 and 20. The specification states that "[t]he at least one pharmaceutically acceptable excipient can be chosen from, *for example*, . . . binders *such as* povidone, hydroxypropyl methylcellulose, dihydroxy propylcellulose, and sodium carboxyl methylcellulose." *See* '405 patent, Rothman Decl. Ex. 1, col.6 l.57-col.7 l.9 (emphasis added). Neither this listing of exemplary binders nor anything else in the specification suggests that unlisted binders are excluded from the claimed pharmaceutical compositions entirely.

Moreover, the '405 patent file history supports Amgen's position that the claims are not closed to unlisted binders. This is shown through the various Notices of Allowability where the Examiner expressly relied upon "nature of the excipients and their respective amounts" in allowing the claims. The examiner focused not on the exclusion of unlisted excipients, but rather on the "***precise amounts*** of calcium receptor-active compound (cinacalcet HCl)," and "the ***nature of the excipients*** and their respective combinations" to provide "good bioavailability and rapid dissolution of cinacalcet HCl." (Rothman Decl. Ex. 5 at SENS-AMG00001593 (emphasis added).) At no point did the examiner indicate that the inclusion of specific, individual binders in element (c) to the exclusion of other binders was a factor in allowance. In subsequent notices of allowance (entered after requests for continued examination), the Examiner reiterated and

further explained the same reasons for allowance, focusing on the precise amount of cinacalcet HCl, the nature of the excipients, and the good bioavailability and rapid dissolution of the formulation. (Rothman Decl. Ex. 6 at SENS-AMG00001069-70, Rothman Decl. Ex. 7 at SENS-AMG00001648-1650, Ex. 5 at SENS-AMG00001593-94) In sum, nothing in the prosecution history suggests that unlisted binders are excluded from the claimed compositions entirely.

4. Collateral Estoppel Does Not Apply

Accord may argue that Amgen is collaterally estopped from advancing its construction of the binder limitation, but this is incorrect. Collateral estoppel ("issue preclusion") prevents an issue of law or fact actually litigated and decided by a court of competent jurisdiction in a prior action from being relitigated in a subsequent suit by the same party or its privies. *United States v. Stauffer Chem. Co.*, 464 U.S. 165, 170–71 (1984). As articulated by the Third Circuit, collateral estoppel only applies if all six of the following elements are found: (1) the identical issue was previously decided; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; (4) the party being estopped was fully represented in the prior action; (5) the party being estopped had a full and fair opportunity to litigate the issue in the prior action; and (6) the issue was determined by a final and valid judgment. *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006). "Redetermination of issues is warranted if there is reason to doubt the quality, extensiveness, or fairness of procedures followed in prior litigation." *Montana v. United States*, 440 U.S. 147, 164 n.11 (1979). For collateral estoppel to apply, the party against whom preclusion is sought must have had a full and fair opportunity to litigate during the prior proceeding procedurally, evidentially, and substantively. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333 (1971).

As an initial matter, the claim construction rulings in case No. 1:16-cv-00853-MSG, which Amgen is currently appealing, are not final judgments, and are therefore not preclusive in

this Court. *See Amgen, Inc. v. Mylan, Inc.*, No. 2:17-CV-01235, 2018 WL 6061213, at *5 (W.D. Pa. Nov. 20, 2018) ("the claim construction rulings that Amgen appealed are not final judgments and are thus not preclusive in" the District Court); *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1357-58 (Fed. Cir. 2017) (explaining that "the claim constructions became final when [the Federal Circuit] affirmed them on appeal.") (emphasis added). Because claim construction rulings that are subject to a pending appeal are not final, Amgen is not estopped from arguing for its construction of element (c) here.

In addition, collateral estoppel does not apply to the Court's previous claim construction ruling because Amgen did not have a full and fair opportunity to litigate the construction of the binder limitation in the previous 16-853-MSG action procedurally, evidentially, and substantively for two primary reasons: (1) no expert testimony was allowed to be submitted on the understanding of a POSA of the binder limitation and (2) Amgen was denied a full and fair opportunity to have a *Markman* hearing regarding the proper construction of the binder limitation.

First, expert testimony could have assisted the Court in the previous action in understanding how a POSA would have understood the binder limitation in the context of the claims of the '405 patent. Dr. Williams, an expert in pharmaceutical formulation, has submitted a declaration to assist the court with certain scientific issues concerning a POSA's understanding of the pharmaceutical compositions claimed in the '405 Patent. *See Phillips*, 415 F.3d at 1318. Indeed, as the Federal Circuit has warned, "failure to take into account the testimony of persons of ordinary skill in the art may constitute reversible error." *AFG Indus.*, 239 F.3d at 1249.

Second, a *Markman* hearing is essential to the determination of a disputed claim term. *See Shuffle Master v. Vendingdata Corp.*, No. 2:04-CV-01373-BES-LRL, 2007 WL 674290, at

*2 (D. Nev. Feb. 28, 2007) ("There is little doubt that claim construction is of essential importance in nearly every patent case. The recognition of this fact is what motivates courts to hold *Markman* hearings in the first place."). Indeed, the Federal Circuit has held that when a previous court construed a claim term without oral argument or a *Markman* hearing, collateral estoppel did not apply to prevent that same claim term from being construed in a later action. *See RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1262 (Fed. Cir. 2003) (finding that, because "there is no evidence that an evidentiary hearing was conducted to construe the claims" and no oral argument was held regarding claim construction, collateral estoppel did not prevent the Alabama district court from "adopting a claim construction contrary to that made by the Virginia district court" because it was "questionable whether the parties were 'fully heard' before the Virginia district court reached its decisions on claim constructions"); *see also Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (applying Federal Circuit precedent to collateral estoppel analysis when claim construction is involved).

In the 16-853-MSG action, the proceedings were plainly inadequate to give Amgen a full and fair opportunity to litigate the proper construction of the binder limitation. The Court took up claim construction issues at the pretrial conference on the eve of trial without affording Amgen the opportunity to brief its claim construction arguments in advance of a scheduled hearing. The Court allowed Amgen only approximately ten minutes to argue the issue at the pretrial conference followed by a short three-page letter brief, which was permitted after Amgen's counsel requested the opportunity to file a written submission. (*Amgen, Inc. v. Aurobindo Pharma, Ltd. et al.*, C.A. No. 16-853-MSG, Transcript of Pretrial Conference, at 75:8-10, 79:24-80:14, 81:15-24, 83:14-23 (Feb. 16, 2018).) And although Amgen filed a motion for reargument of the claim construction issue, that motion was denied and Amgen was still not

permitted to submit any expert testimony. *See* D.I. 323 in C.A. No. 16-853-MSG. Thus, Amgen did not have a full and fair opportunity procedurally, evidentially, and substantively to litigate its claim construction position concerning the binder limitation because it did not have the opportunity to present expert testimony or participate in proper *Markman* proceedings. *Blonder-Tongue*, 402 U.S. at 333 (no estoppel should apply where "without fault of his own the patentee was deprived of crucial evidence or witnesses in the first litigation").

Finally, the Supreme Court has made clear that no situation automatically gives rise to estoppel: "[A]s so often is the case, no one set of facts, no one collection of words or phrases, will provide an automatic formula for proper rulings on estoppel pleas. In the end, the decision will necessarily rest on the trial courts' sense of justice and equity." *Blonder-Tongue*, 402 U.S. at 333–34. In this area of law, where "claim construction often involves a fluid process," equity favors not precluding Amgen from rearguing its claim construction position with regard to the binder limitation. *See, e.g.*, *Cadence Pharm., Inc. v. Innopharma Licensing LLC*, No. 14-1225-LPS, 2016 WL 3661751, at *3 (D. Del. Jul. 8, 2016); *see also Jack Guttman, Inc. v. KopyKake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."). The Court should revisit its claim construction ruling in the previous action regarding the binder limitation with the assistance of testimony from the perspective of a POSA (Dr. Williams) regarding the technology at issue and oral argument during a *Markman* hearing.

B. The Claimed Binders Are Binders Capable of Forming Liquid Bridges That Harden Upon Drying

1. Construction Is Needed for the Court to Properly Decide Other Issues in the Litigation

As stated in Amgen's opposition to Accord's motion for summary judgment (D.I. 41 at 3-4), the Court must construe the claims before defining the field of foreseeable equivalents, and before determining whether Accord's alleged binder would have been an unforeseeable equivalent to the listed binders of claims 1 and 20 at the relevant time. Thus, construction of this aspect of element (c) is necessary because the Court must ascertain the scope of the claims 1 and 20 before issues concerning infringement under the doctrine of equivalents, prosecution history estoppel, and the field of foreseeable equivalents are analyzed.

2. The Intrinsic Evidence Supports Amgen's Proposed Construction

The binder element in the claims provides the four binders listed in the specification: povidone, HPMC, hydroxypropyl cellulose, and sodium carboxymethylcellulose. The '405 patent specification notes granule formulation using wet techniques, such as wet granulation and spheronization. D.I. 1-1, col.9 ll.42-45. A POSA would have known that to create a tablet, powdered ingredients are compressed into the shape of tablet. Very fine powders may not be sufficiently compressible for tableting, and in such cases the powders must be granulated. Granulation is the process of agglomerating these fine particles into larger "granules." Williams Decl. ¶19. A POSA would have known that wet granulation is one of the most common granulation techniques, and involves adding a liquid solution to powders. *Id.* ¶20. In wet granulation, granules are formed by adding a liquid called a "granulation liquid" or "granulating fluid" to the powder while the powder is agitated by an impeller, air, or other means. *Id.* The agitation and wetting of the powdered components, under the right conditions, causes the powder

to agglomerate into larger "granules." *Id.* Such granules, if properly formed, may contribute to the desired features of a formulation, such as a desired dissolution profile.

Based on the claim language itself, a POSA would have understood that the excipients listed in element (c) could all function as binders in pharmaceutical formulations prepared using wet processing techniques and have binding attributes in common when used in compositions (i.e., tablets) formed using these techniques. *Id.* ¶¶21-23. In particular, povidone, HPMC, hydroxypropyl cellulose, and sodium carboxymethylcellulose all function as hardening binders. *Id.* ¶25. These binders can be included in the granulating solvent or the solvent can be used to mass the powder containing these binders. *Id.* In either case, the liquid will form liquid bridges, and the adhesive is capable of hardening or crystallizing on drying to form solid bridges to bind the particles as the solvent is removed. *Id.* Thus, all four excipients listed in the binder limitation can function as hardening binders, that is, they are capable of forming liquid bridges that harden upon drying in pharmaceutical compositions. *Id.*

The '405 patent specification also supports Amgen's proposed construction. The specification expressly mentions the word "binder" twice: First, in a description of the types of pharmaceutically acceptable excipients that may be used, while providing an exemplary list of potential binders (featuring the use of "such as") (D.I. 1-1, col.6 l.57-col.7 l.9), and second, in an exemplary embodiment of the invention (*id.* col.7 ll.32-49). As understood by a POSA, the exemplary list of binders provided in the specification (povidone, HPMC, dihydroxy propylcellulose, and sodium carboxyl methylcellulose) all have the common property of being capable of forming liquid bridges that harden upon drying. Williams Decl. ¶24-25. Thus, the intrinsic evidence supports Amgen's proposed construction.

IV. "hydroxypropyl methylcellulose"

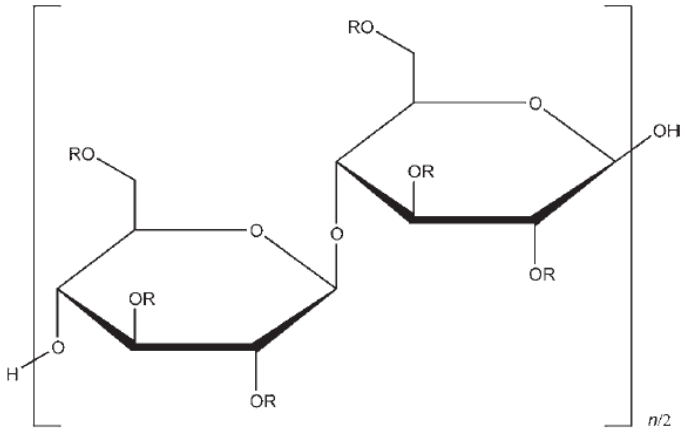
Claim Term	Amgen's Proposed Construction	Accord's Proposed Construction
"hydroxypropyl methylcellulose" *(claims 1, 20)*	"any hydroxypropyl methylcellulose that is present in the composition"	"hydroxypropyl methylcellulose"

The Parties' dispute over the meaning of the term "hydroxypropyl methylcellulose" ("HPMC") in element (c) of claims 1 and 20 is directly related to their disputed infringement and non-infringement contentions. Amgen contends that Accord's product literally infringes element (c) because its product contains a certain percentage of Opadry, a commercially available excipient that is a mixture of mostly HPMC and small amounts of other ingredients. (D.I. 52 at 3). Accord denies that the HPMC in Opadry satisfies element (c) and, despite the parties' evident dispute, contends that the claim requires no further construction.

But the scope of this claim term is fundamental to the Court's ultimate infringement analysis. Where the parties dispute the meaning of a claim term, it is appropriate for the Court to construe the term according to its plain and ordinary meaning rather than simply pronounce that it should be given its plain and ordinary meaning or requires no construction. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1318 (Fed. Cir. 2016) (determination that a term "needs no construction" or has the "plain and ordinary meaning" may be inadequate when a term has more than one "ordinary" meaning or when reliance on a term's "ordinary" meaning does not resolve the parties' dispute). Indeed, because the scope of this term is in dispute and directly impacts the infringement analysis, it requires construction. *See O2 Micron Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it.").

Adopting Accord's construction of "hydroxypropyl methylcellulose" does not resolve the parties' dispute over the meaning of the term, and will result in the Court having to determine the plain and ordinary meaning at a later date, potentially on the eve of trial or during trial. Instead, the Court should adopt Amgen's proposed construction: "any HPMC that is present in the composition," i.e., regardless of whether it is added alone or premixed with other ingredients. This is consistent with how a POSA would have understood the term "HPMC," within the context of the claim directed to pharmaceutical compositions. A POSA would have understood HPMC to refer to any HPMC present in a pharmaceutical composition, regardless of how it was added to the composition or whether it was premixed with other substances before being added, i.e., any HPMC "that is present in the composition."

HPMC, also known as hypromellose, is a polymer that has the structural formula depicted below:



where R is H, CH_3, or $CH_3CH(OH)CH_2$

Williams Decl. ¶¶31-32. A POSA would have known that HPMC is available as both a standalone product consisting of about 100% HPMC, and as products such as "Opadry Green," in which HPMC is pre-mixed with other ingredients. *Id.* ¶33. These products contain HPMC and additional ingredients. *Id.*

Chemically, there is no difference between the HPMC in a standalone product and the HPMC in a premixed product such as Opadry Green. *Id.* ¶34. The HPMC in premixed products is the same chemical substance as is contained in standalone HPMC products. *Id.* A POSA would have understood the term "HPMC" to refer to any HPMC present in a pharmaceutical formulation, regardless of how it was added to the formulation or whether it was premixed with other substances before being added, i.e., any HPMC "that is present in the composition." *Id.* ¶35.

The intrinsic record supports the POSA's understanding of this term within a pharmaceutical composition. The '405 patent specification mentions both HPMC (D.I. 1-1, col.6 ll.57-64, col.7 ll.28-31) and products that contain HPMC such as Opadry® II (green) and Opadry® Clear (*id.* col.11 l.37, col.11 ll.39-40, col.12 ll.21-26, fig.1). Nowhere in the specification or file history is HPMC limited to a specific type of HPMC, or a specific product containing HPMC. Moreover, HPMC is noted in the specification as having at least two functions: as a binder (*id.* col.6 l.57-col.7 l.9) and as a coating material (*id.* col.7 ll.28-31), showing its multifunctional nature as an excipient in pharmaceutical compositions. As a coating material specifically, the '405 patent specification mentions both HPMC itself (*id.* col.7 ll.28-31) and separately lists Opadry® II (green) and Opadry® Clear (*id.* col.11 l.37, col.11 ll.39-40, col.12 ll.21-26, fig.1), products which contain HPMC as its primary ingredient. *See* Williams Decl. ¶33. This demonstrates that the '405 patent acknowledges HPMC may come in many different forms, and the claims are therefore not limited to a specific source of HPMC, but any HPMC present in the composition.

CONCLUSION

Amgen respectfully requests that the Court adopt Amgen's proposed constructions of the disputed claim terms. Amgen also respectfully requests a claim construction hearing.

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June 28, 2019

CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 28, 2019, upon the following in the manner indicated:

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